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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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C. R. Bard, Inc.
Bard Peripheral Vascular, Inc.
1415 W. 3rd Street
P.O. Box 1740
Tempe, AZ 85280-1740

EXAMINER	
LLOYD, EMILY M	

ART UNIT	PAPER NUMBER
3736	

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11/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,518	HESKE ET AL.	
	Examiner	Art Unit	
	EMILY M. LLOYD	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-100* is/are pending in the application.

4a) Of the above claim(s) *58-65 and 69-97* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57,66-68 and 98-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to Applicant's 31 July 2009 amendment. The Examiner acknowledges Applicant's amendments to the specification, the replacement drawings, and the amendments to claims 57, 66-68 and 98-100. Currently, claims 57-100 are pending, and claims 58-65 and 69-97 are withdrawn from prosecution.

Information Disclosure Statement

2. The Examiner notes that, as indicated on the Information Disclosure Statements of 29 June 2004 and 11 October 2005 sent with the previous Office Action, the references in these Information Disclosure Statements, except where lined through, were considered. If Applicant would like the lined through references considered, Applicant is required to submit an additional IDS along with a concise explanation of relevance in English. See 37 CFR 1.98 (a)(3)(i).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 66-68 and 100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 66, it is unclear if "a respective intermediate portion of the removable element" is the hollow connecting element, or if this could be any portion of the removable element towards the center of the removable element, or if this could be any portion of the removable element that is not at the distal end of the removable element. Claims 67 and 68 are rejected as depending on claim 66.

Regarding claim 67, it is unclear if "a front portion of the removable element" is the biopsy needle, the pressure source, a specific portion of the biopsy needle or pressure source, or another structure.

Regarding claims 68 and 100, it is unclear if a structure which has a portion extending outside its housing (claims 68 and 100 "at least a portion of the hollow connecting element extends between the first U-shape opening and the second U-shape opening (external to the housing)") is also "self-contained" (claims 57 and 98).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 57, 98 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gregoire et al. as modified by Dejter, Jr et al..

Regarding claim 57, Gregoire et al. disclose a biopsy device for tissue collection (Figures 1-7 and 14), comprising: a housing (housing 31a Figure 1); and a removable element (probe 45 Figure 1 and Column 5 lines 30-44, probe 45a Figure 14), comprising a biopsy needle module (elongated hollow piercing needle 51, cutter 60 and tissue extractor 65 Figure 2), wherein the removable element is configured for integration into the housing (Figure 1 and Column 5 lines 30-44), and a hollow connecting element communicatively coupled between the biopsy needle module and the pressure source (vacuum line 85 Figure 2), wherein the biopsy device is configured for entirely single-handed operation by a physician (operating or controlling the device is

done by a single hand, Column 10 lines 8-10, further, when the device is attached to the table the operation of the device would clearly be performed with a single hand).

As Gregoire et al.'s probe drive 31 contains a motor (Column 6 lines 40-42), it is clear that Gregoire et al. comprises a power source (in order to power the motor) but it is unclear where the power source is located. Further, it also appears that probe drive 31 can be held in a single hand of a physician. However, Dejter, Jr et al. explicitly teaches a housing (casing 1 Figure 13) containing a power source (battery 92 (not shown) in chamber 90 Figure 13); and a removable element (disposable syringe assembly Column 4 lines 8-10), comprising a pressure source (syringe 4 and plunger 5 Figure 13) with the pressure source being contained within the housing (syringe 4 and plunger 5 Figures 1a-1f); and that the biopsy device is self-contained (Figure 13) and has no cables or lines extending from the housing to external units (Figure 13). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the power source in the housing, the removable element comprising a pressure source, the pressure source being contained within the housing, and the biopsy device being self-contained and having no cables or lines extending from the housing to external units as taught by Dejter, Jr et al with the invention of Gregoire et al. as this would provide for a single person performing the biopsy procedure (Dejter, Jr et al. Column 2 lines 45-48), and would provide for the biopsy to be performed in an outpatient setting (Dejter, Jr et al. Column 2 lines 48-53) without the need or concern for external equipment requirements (it is easier to set up and perform a biopsy when only a single apparatus is required as opposed to external vacuum sources, control units,

etc.). Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make Gregoire et al. portable with the teachings of Dejter, Jr et al. as this would not provide new or unexpected results. See MPEP 2144.04 V A Making Portable.

Regarding claim 98, Gregoire et al. as modified by Dejter, Jr et al. disclose the biopsy device of claim 57 (see 103(a) rejection of claim 57 by Gregoire et al. as modified by Dejter, Jr et al.), and further disclose that the housing comprises a lower housing segment (Gregoire et al. portion of housing 31a below cover 38 Figure 1; also Dejter, Jr et al. portion of casing 1 below cover 82 Figure 13) with lateral walls (Gregoire et al. walls of housing 31a leading up to cover 38 Figure 1; also Dejter, Jr et al. walls of casing 1 leading up to cover 82 Figures 14 and 15), a housing lid matched to the lower housing segment (Gregoire et al. cover 38 Figure 1; also Dejter, Jr et al. cover 82 Figures 1-15) and having a locking mechanism (Dejter, Jr et al. latch 89 and release button 83 Figure 15 and Column 10 line 64-Column 11 line 7), and a first end lid and a second end lid (Gregoire et al. walls of housing 31a at the distal and proximal portions of the device (where back plate 36 is one end lid; the portion opposite back plate 36 is the other end lid) Figure 1; also Dejter, Jr et al. distal portion of casing 1 near connections 11, 81, and proximal portion of casing 1 between power switch breaker 111 and origin sensor 120 Figure 13), each connected to the lower housing segment (Gregoire et al. housing 31a is connected to back plate 36 and the portion opposite back plate 36, Figure 1; also Dejter, Jr et al. the distal and proximal ends are connected to casing 1). Further, Gregoire et al. as modified by Dejter, Jr et al. are moot as to the

direction of the locking mechanism. However, assuming that such a direction is not already longitudinally displaceable, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have such a locking mechanism be longitudinally displaceable as this is a simple rearrangement of parts regarding the positioning/direction of the locking mechanism that would not have modified operation of the device, and the direction of displacement of the locking device is an obvious matter of design choice. See MPEP 2144.04 VI C Rearrangement of Parts.

Regarding claim 99, Gregoire et al. as modified by Dejter, Jr et al. teach the biopsy device of claim 98, including a first end lid comprising a U-shaped opening at the top thereof, the opening sized to receive a portion of the removable element (Gregoire et al. probe slot 39 and tissue extractor 65 Figures 6 and 7).

Response to Arguments

9. Applicant's arguments filed 31 July 2009 with regards to claims 57, 98 and 99 have been fully considered but they are not persuasive.

10. Regarding Applicant's argument that the limitation of "a hollow connecting element communicatively coupled between the biopsy needle module and the pressure source" is not found in the prior art, the Examiner notes that the vacuum line of Gregoire et al. meets this limitation.

11. Regarding Applicant's argument that the limitation of "wherein the biopsy device is configured for entirely single-handed operation" is not found in the prior art, the Examiner notes that, as a desk phone, which is usually supported by a desk, but is

capable of being held in one hand and operated by the other, is configured for entirely single-handed operation, Gregoire et al.'s device is also configured for entirely single-handed operation.

12. The Examiner further notes that Dejter, Jr et al. teach a biopsy device that is self-contained.

13. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the probe drive is a handheld device) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

14. With regards to claim 99, the Examiner notes that the first end lid/ back plate 36 of Gregoire et al. provides an opening that meets the Applicant's limitations.

15. Applicant's arguments with respect to claims 66-68 and 100 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LLOYD whose telephone number is (571)272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd
Examiner
Art Unit 3736

/EML/

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736